Appendix 4. Summary of Safety and Effectiveness

G2™ Filter System – Jugular/Subclavian Delivery Kit
510(k) Summary of Safety and Effectiveness
21 CFR 807.92.

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based as follows:

1. Submitter Information:

Applicant: Bard Peripheral Vascular, Inc
1625 West 3rd Street
P.O. Box 1740
Tempe, Arizona 85280

Phone: 480-303-2524

Fax: 480-449-2546

Contact: Genevieve Balutowski,
Senior Regulatory Affairs Specialist

2. Subject Device Name:

Device Trade Name:	**G2™ Filter System – Jugular/Subclavian Delivery Kit**
Common or Usual Name:	Vena Cava Filter
Classification:	Class II
Classification Panel:	Cardiovascular

3. Predicate Device:

G2™ Filter System – Femoral Delivery Kit (K050558, cleared 8/29/05)

4. Summary of Change:

The design modification to the G2™ Filter System – Jugular/Subclavian Delivery Kit as represented in this submission is an additional delivery system. The G2™ Filter component of the subject device remains the same as the predicate device.

5. Device Description:

The G2™ Filter System – Jugular/Subclavian Delivery Kit allows for placement of the G2™ Filter via a Jugular or Subclavian vein approach. The G2™ Filter System – Jugular/Subclavian Delivery Kit consists of a dilator and introducer set and a delivery device with a preloaded filter. The dilator accepts a 0.038" guidewire and enables a contrast medium power injection up to 800 psi maximum pressure. The 10 French I.D. introducer sheath contains a radiopaque tip and hemostasis valve with a side port for injecting contrast medium via a syringe. The delivery device fits within the introducer sheath and consists of a side port for saline infusion and a delivery mechanism to deploy the G2™ Filter. The delivery device contains a spline cap that mechanically separates the filter hooks from one another in a unique pattern to prevent leg entanglement.

6. Intended Use of Device:

The G2™ Filter System – Jugular/Subclavian Delivery Kit is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The subject device has the same intended use and indications of use as the predicate device, the G2™ Filter System - Femoral Delivery Kit (K050558, cleared 08/29/05).

7. Technological Comparison to Predicate Device:

The technological characteristics of G2™ Filter System – Jugular/Subclavian Delivery Kit are substantially equivalent to those of the predicate device, the G2™ Filter System – Femoral Delivery Kit, in terms of intended use, indication for use, application, user population, basic design, performance, and sterilization method.

8. Conclusions:

The G2™ Filter System – Jugular/Subclavian Delivery Kit met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The G2™ Filter System – Jugular/Subclavian Delivery Kit is substantially equivalent to the legally marketed predicate device, the G2™ Filter System – Femoral Delivery Kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 2005

Bard Peripheral Vascular, Inc.
Ms. Genevieve Balutowski
Senior Regulatory Affairs Specialist
P.O. Box 1740
Tempe, AZ 85280

Re: K052578
Trade Name: G2 Filter System
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II (two)
Product Code: DTK
Dated: October 25, 2005
Received: October 26, 2005

Dear Ms. Balutowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions section of the device's labeling and in promotional materials:

> The safety and effectiveness of the G2 Filter System for use as a retrievable or temporary filter have not been established.

Furthermore, the indication for permanent placement of the G2 Filter System must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: G2™ Filter System – Jugular/Subclavian Delivery Kit

Indications for Use:

The G2™ Filter System – Jugular/Subclavian Delivery Kit is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

Prescription Use__X__ AND/OR Over-The-Counter Use_____
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vedrnel

(Division Sign-Off)
Division of Cardiovascular Devices

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